

FDA Issues Final Rule to Protect Food from Intentional Adulteration

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On May 27, 2016, FDA finalized its seventh and final food safety rule under the Food Safety Modernization Act (FSMA),¹ which will become new 21 C.F.R. Part 121.² The Intentional Adulteration rule establishes requirements to help protect food against adulteration from acts intended to cause wide-scale harm to public health, including acts of terrorism. For the first time, domestic and foreign food facilities will be required to complete and maintain written food defense plans assessing their potential vulnerabilities to deliberate contamination where the intent is to cause wide-scale public health harm.

The proposed rule was issued on December 24, 2013.³ After considering over 200 comments from stakeholders and others, FDA incorporated several changes into the final rule to give industry additional flexibility and a longer timeline for compliance. This client alert summarizes the highlights of the final rule and issues most likely to impact industry.

Background

In developing the rule, FDA concluded that although intent to cause public harm via intentional adulteration of the food supply is unlikely, it could have catastrophic results if it did occur, including illness, death, and economic disruption of the food supply. FDA therefore has focused the final rule only on acts of intentional adulteration designed to cause large-scale public harm. Consequently, the rule does not apply to acts of intentional adulteration caused by disgruntled employees, consumers, or competitors that do not have this intent. The rule likewise does not address economic adulteration, which is instead addressed in FDA's final preventive controls rules for human and animal foods.⁴

¹ FSMA was signed into law on January 4, 2011. Click [here](#) for our client alert issued when FSMA was enacted that described its key provisions.

² Mitigation Strategies to Protect Food Against Intentional Adulteration, 81 Fed. Reg. 34166 (May 27, 2016), available [here](#). The final rule implements the intentional adulteration provisions in sections 418, 419, and 420 of the Federal Food, Drug, and Cosmetic Act (FDCA). FDA's webpage on the final rule, including a fact sheet, explanatory diagram, and additional information, can be found [here](#).

³ 78 Fed. Reg. 78014 (Dec. 24, 2013).

⁴ Click [here](#) for our client alert on preventive controls for human foods; click [here](#) for our client alert on preventive controls for animal foods.

Instead of targeting specific foods or hazards, the rule requires covered food facilities to implement risk-reducing strategies for certain processes. Like the proposed rule, the final rule follows a hazard analysis critical control point (HACCP) type approach that requires an analysis of hazards/vulnerabilities susceptible to intentional adulteration and the implementation of measures to mitigate the identified hazards/vulnerabilities.

Facilities to Whom the Rule Applies; Exempted Facilities

With few exceptions, the rule applies to both domestic and foreign facilities required to register under section 415 of the Federal Food, Drug, and Cosmetic Act (FDCA), and is designed to cover large companies whose products reach many people. Generally, the rule exempts the following:

- Very small businesses (that make < \$10,000,000 in total annual sales of food, adjusted for inflation).⁵
- Facilities that only hold food, except liquid food storage tanks.
- Facilities that pack, re-pack, label, or re-label food where the container that directly contacts the food remains intact.
- Farms.
- Animal food facilities.
- Alcoholic beverages under certain conditions.
- On-farm manufacturing, processing, packing, or holding by small or very small businesses identified as having low-risk foods.

Scope of the Rule

The rule requires covered facilities to: (1) conduct an assessment of vulnerable processes in their operations susceptible to acts that could cause large-scale public harm; (2) prepare and implement a written food defense plan; (3) conduct personnel training; and (4) prepare and keep written records.

Conduct a Vulnerabilities Assessment

Covered facilities must identify vulnerabilities and actionable process steps for each type of food manufactured, processed, packed, or held at the food facility. The requirements for vulnerability assessments differ from those of the proposed rule, in which FDA had identified specific areas of vulnerability as processes that required focused mitigation strategies (bulk liquid receiving and loading, liquid storage and handling, secondary ingredient handling, and mixing and similar activities). In contrast, in the final rule, the agency specifies three elements that, as a minimum, covered facilities must evaluate when conducting a vulnerability assessment:

⁵ These businesses are exempt from the rule, but must provide to FDA, upon request, documentation demonstrating the business is very small.

- The potential impact on public health of an attack on the product.
- The degree of physical access to the product.
- The ability of an attacker to successfully contaminate the product.

Prepare and Implement a Written Food Defense Plan

The rule requires covered facilities, for the first time, to prepare and implement a written food defense plan, which must include:

- A written vulnerability assessment, including required explanations, to identify significant vulnerabilities and action steps; and
- For any significant vulnerabilities that the assessment identifies:
 - Written mitigation strategies, including required explanations;
 - Written procedures for monitoring;
 - Corrective action procedures; and
 - Written verification procedures.

Covered facilities that identify significant vulnerabilities must identify and implement mitigation strategies at each actionable process step to provide assurances that each vulnerability will be significantly minimized or prevented and that food manufactured, processed, packed, or held by the facility will not be adulterated. In addition, the rule requires covered facilities to monitor the mitigation strategies and to include in the written food defense plan the frequency with which such monitoring is to be performed. Covered facilities must also use corrective actions if mitigation strategies are not properly implemented and to verify that monitoring is being conducted and appropriate decisions about corrective actions are being made. Compared to the proposed rule, the final rule provides more flexibility to industry in incorporating mitigation strategy management components (food defense monitoring, corrective actions, and verification).

In addition, the rule requires each covered facility to conduct a reanalysis of its food defense plan at least every three years or under certain specified conditions.

Conduct Personnel Training

Covered facilities must train personnel and supervisors assigned to the actionable process steps in food defense awareness and in their responsibilities for implementing mitigation strategies.

Prepare and Keep Records

Finally, the rule requires covered facilities to establish and maintain certain records, including: the written food defense plan; records documenting monitoring, verification activities, and corrective actions; and documentation related to the training of personnel. Facilities must retain records for at least two years after the date they were prepared, except for the food defense plan, which must be retained for at least two years after its use is discontinued.

Compliance and Compliance Dates

The rule prescribes tiered compliance dates, depending on the size of the business, as follows:

- Very Small Businesses: businesses with less than \$10,000,000 in total annual sales of food have five years after the effective date to compile documentation sufficient to show that the facility meets the very small business exemption, until July 26, 2021.
- Small Businesses: businesses employing fewer than 500 persons but that do not meet the definition of “very small business” have four years after the effective date to comply, until July 26, 2020.
- Other Businesses: businesses that are not small, and do not qualify for any other exemptions, have three years after the effective date to comply, until July 26, 2019.

Compared to the proposed rule, these dates offer two years of additional compliance time to each tier in response to industry concerns that they will not have adequate time or resources to implement requirements for the intentional adulteration rule at the same time they must comply with other FSMA rules.

Assistance to Industry

To assist industry in complying with the rule, FDA has established an Intentional Adulteration Subcommittee with the Food Safety Preventive Controls Alliance to develop food defense training resources for both industry and regulators. The agency also intends to publish guidance documents assisting industry in complying with the rule, such as guidance documents on conducting a vulnerability assessment, identifying and implementing mitigation strategies, and writing procedures for food defense monitoring, corrective actions, and verification. In addition to various tools offered on FDA’s website,⁶ the agency is offering a webinar regarding the rule on June 21, 2016.⁷

⁶ FDA’s website has several tools available to assist industry in complying with the rule. Click [here](#) for FDA’s food defense resources; click [here](#) for FDA’s Mitigation Strategies Database. Click [here](#) for FDA’s FSMA Food Safety Technical Assistance Network webpage.

⁷ Details on the June 21, 2016, webinar can be found [here](#).

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Covington is experienced in advising clients on legal matters related to conventional foods and dietary supplements and is available to provide individualized compliance counseling concerning these issues. If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food & Drug practice group:

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